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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/398,253 09/17/99 NEHLS

M 8535-026-999

020583 HM22/0703
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER

KIM, Y	
ART UNIT	PAPER NUMBER

1631
DATE MAILED:

13
07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<p align="center">Office Action Summary</p>	Application No. 09/398,253	Applicant(s) NEHLS ET AL.	
	Examiner Young J. Kim	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,10 and 11 is/are rejected.
- 7) ☒ Claim(s) 1,11 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

This Office Action responds the Amendment received on April 11, 2001 (Paper No. 12).

Preliminary Remark

The cancellation of claim 2 is acknowledged. The newly submitted claims 5 and 6 have been renumbered to 10 and 11 under Rule 1.182.

Claim Objections

Claim 1 (and the dependents thereon) objected to because of the following informalities:

Claim 1 appears to be missing a conjunction after the SEQ ID Number 17 to read "17, and 18."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the Office Action mailed on October 11, 2000 is withdrawn in view of the Amendment received on April 11, 2001.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 1-4 and (newly submitted claims 10 and 11) under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility, in the Office Action mailed on October 11, 2000 is maintained for the reasons of record.

Applicants' argument filed on April 11, 2001 have been fully considered but they are not found persuasive. Applicants argue that the claimed oligonucleotide can be used to expand the utility of current genomic data such as human genomic data, such as identifying the expressed genes in raw sequences, identification of expressed genes (bottom paragraph, pp. 4), even poorly expressed genes (1st paragraph, pp. 5), diagnostic of gene expression (2nd paragraph, pp. 4), cross species hybridization analysis (2nd paragraph, pp. 4), and gene mapping (3rd paragraph, pp. 4 and 1st paragraph, pp. 5), ultimately resulting in the expanding the utility of genomic data, and to expand the utility of current mapping techniques (2nd paragraph, pp. 6).

On the contrary, the claimed nucleic acids do not have a specific utility. A nucleic acid, could certainly be used as a probe for detecting a condition, a primer for amplifying a region which would serve as an indication of something, determining the location of a corresponding DNA sequence on a physical or genetic map and thus determining the function of a gene, etc. The claimed nucleic acid lacks specific utility because the nucleic acids are not disclosed as being useful as a probe for detecting a specific clinical condition. Simply stating that a nucleic acid could be used as a probe, primer, or anything, does not constitute a specific utility because any piece of nucleic acid would invariably hybridize to another piece of nucleic acid. The result of its hybridization, however, does not produce any real world application useful to one of ordinary skill in the art. The real world application of nucleic acid are not amplifying anything

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or hybridizing to anything. It must, by its hybridization, or amplification (primer usage), etc., infer a useful information. It is that useful information which would give any nucleic acids a specific utility. Simply stating that a nucleic acid has utility because it does something that's well recognized in the art (such as hybridizing to something) is not specific because one of ordinary skill in the art would not recognized what the nucleic acid is useful for. Expounding on the probe example, the probe's hybridization to its target nucleic acid would have to lead to a real world application that is useful to one of ordinary skill in the art for the utility to be specific.

Therefore, it is determined that the polynucleotides of the instant application lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-4 (and newly filed claims 10 and 11) under 35 U.S.C. 112, first paragraph because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in the Office Action mailed on October 11, 2000 is maintained for the reasons of record.

Applicants' argument filed on April 11, 2001 have been fully considered but they are not persuasive for the reasons already set forth above.

The rejection of claims 1-4 (and newly filed claims 10 and 11) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention in the Office Action mailed on October 11, 2000 is maintained for the reasons of record.

Applicants' argument filed on April 11, 2001 have been fully considered but are not found persuasive.

Applicants argue that the claims recite synthetic oligonucleotides or isolated polynucleotides corresponding to one of the elected SEQ ID Numbers (pp. 7) and that one of skill in the art can readily distinguish the synthetic oligonucleotides of the claims from other materials by the structural description of claim 1. This is not found persuasive because the specification does not describe a clear demarcation (i.e, length) of what an oligonucleotide would comprise.

The written description rejection was made because it was not apparent from the specification that claimed SEQ ID Numbers contain a complete open reading frame. Thus, barring evidence to the contrary, the nucleic acid comprising the claimed SEQ ID Numbers would read on undiscovered genes and nucleic acid sequences from other species, allelic variants, and so forth which are clearly not described by the disclosure of the instant application as such sequences would comprise the claimed SEQ ID Numbers. If the SEQ ID Numbers claimed by Applicant do contain complete open reading frames, and evidence is provided, the rejection will be withdrawn.

Claim Rejections - 35 USC § 102

The rejection of claims 1-2 under 35 U.S.C. 102 (b) as being anticipated by Hillier et al. (1996) in the Office Action mailed on October 11, 2000 is withdrawn in view of the Amendment received on April 11, 2001, canceling the anticipated SEQ ID Number 16.

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Williams et al. (1989) in the Office Action mailed on October 11, 2000 is withdrawn in view of the Amendment received on April 11, 2001, canceling the rejected claim 2.

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Chen et al. (1995) in the Office Action mailed on October 11, 2000 is withdrawn in view of the Amendment received on April 11, 2001, canceling the rejected claim 2.

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by National Cancer Institute, Cancer Genome Anatomy Project (NCI-CGAP) (1997), in the Office Action mailed on October 11, 2000 is withdrawn in view of the Amendment received on April 11, 2001, canceling the rejected claim 2.

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Iturriaga et al. (1998) in the Office Action mailed on October 11, 2000 is withdrawn in view of the Amendment received on April 11, 2001, canceling the rejected claim 2.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2 under 35 U.S.C. 102 (b) as being anticipated by Adams et al. (1997) in the Office Action mailed on October 11, 2000 is maintained for the reasons of record.

Applicants' argument received on April 11, 2001 have been fully considered but are not found persuasive.

Applicants argue that Adams et al. does not teach a synthetic oligonucleotide comprising a contiguous stretch of at least 15 nucleotides (bottom paragraph, pp. 8). The isolated nucleic acid by Adams et al. is from a sequencing method which properly requires the synthesis of nucleotides (NTPs) along the template strands. Thus, the disclosed nucleic acid fully satisfies the limitation implied by the term "synthetic." Unless Applicants can specifically point to a section of the specification where the term oligonucleotide and its clear demarcation are described, the claimed nucleic acid is determined to anticipate the invention as claimed. Therefore, the Sequence Homology Report sent with the Office Action (mailed on October 11, 2000), does disclose a nucleic acid sequence which comprise a stretch of at least 15 nucleotides.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this

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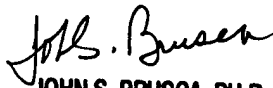
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application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

07/01/01



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER